DRI® Amphetamines Assay

Thermo SCIENTIFIC

IVD **For In Vitro Diagnostic Use**

Rx Only

REF 10014585 (3 x 18 mL)
0017 (100 mL Kit)
0018 (500 mL Kit)

Intended Use

The DRI® Amphetamines assay is intended for the qualitative or semi-quantitative determination of amphetamine and methamphetamine in human urine. The assay has cutoff levels of 500 and 1000 ng/mL. The assay provides a simple and rapid analytical screening procedure for detecting amphetamine and methamphetamine in urine on automated clinical analyzers. The assay is calibrated with methamphetamine.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1,2] Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Summary and Explanation of the Test

Amphetamines are synthetic derivatives of ephedrine. The most common amphetamines include d-amphetamine, d-methamphetamine, and d,l-amphetamine. They act as stimulants for the central nervous system. Amphetamine is the most sympathomimetic amine.[3,4] When amphetamine is ingested, it is either rapidly deactivated in the liver or excreted unchanged into the urine. Other ephedrine derivatives such as methamphetamine can be metabolized and excreted in urine as amphetamine.[5]

The DRI Amphetamines assay is a liquid ready-to-use homogeneous enzyme immunoassay.[6] The assay uses specific antibodies, which can detect amphetamine and/or methamphetamine in urine with minimal cross-reactivity to various over-the-counter structurally unrelated compounds. The assay is based on the competition of an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and the drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds the drug labeled with G6PDH and causes a decrease in enzyme activity. In the presence of free drug, the free drug occupies the antibody binding sites, allowing the drug-labeled G6PDH to interact with the substrate, resulting in enzyme activity. This phenomenon creates a direct relationship between drug concentration in urine and the enzyme activity. The enzyme activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

⚠ Precautions and Warnings

DANGER:
1. This test is for in vitro diagnostic use only. The reagents are harmful if swallowed.
2. Reagents used in the assay components contain ≤0.09% sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with a large volume of water to prevent azide build-up.
3. DRI Amphetamines Assay (100 mL) contains ≤0.5% Drug-specific antibody and ≤0.2% bovine serum albumin (BSA).
4. Do not use the reagents beyond their expiration dates.

H317 - May cause allergic skin reaction.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

Reagents

Antibody/Substrate Reagent: Contains monoclonal anti-amphetamines antibodies, glucose-6-phosphate (G6P), and nicotinamide adenine dinucleotide (NAD) in Tris buffer with sodium azide as a preservative.

Enzyme Conjugate Reagent: Contains amphetamines labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with sodium azide as a preservative.

Reagent Preparation and Storage

The reagents are ready for use. No reagent preparation is required. All assay components when stored at 2-8°C, are stable until the expiration date indicated on the label.

Additional Materials Required (sold separately):

REF	Kit Description
1664	DRI Negative Calibrator, 10 mL
1388	DRI Negative Calibrator, 25 mL
1588	DRI Multi-Drug Calibrator 1, 10 mL
1589	DRI Multi-Drug Calibrator 1, 25 mL
1591	DRI Multi-Drug Calibrator 2, 10 mL
1592	DRI Multi-Drug Calibrator 2, 25 mL
1594	DRI Multi-Drug Calibrator 3, 10 mL
1595	DRI Multi-Drug Calibrator 3, 25 mL
1597	DRI Multi-Drug Calibrator 4, 10 mL
1598	DRI Multi-Drug Calibrator 4, 25 mL
DOAT-2	MAS® DOA Total – Level 2, 6 x 18 mL
DOAT-3	MAS® DOA Total – Level 3, 6 x 18 mL
DOAT-4	MAS® DOA Total – Level 4, 6 x 18 mL
DOAT-5	MAS® DOA Total – Level 5, 6 x 18 mL

Specimen Collection and Handling

Collect urine specimens in plastic or glass containers. Care should be taken to preserve the chemical integrity of the urine sample from the time it is collected until the time it is assayed.

Specimens kept at room temperature that do not receive initial test within 7 days[7] of arrival at the laboratory should be placed into a secure refrigeration unit at 2 to 8°C for several weeks.[8] For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20°C.[9] Studies have shown amphetamine analytes in urine are stable at -20°C indefinitely.[8]

Laboratories following the SAMHSA mandatory guidelines should refer to SAMHSA "Short-Term Refrigerated Storage" and "Long-Term Storage" requirements.[10]

To protect the integrity of the sample, do not induce foaming and avoid repeated freezing and thawing. An effort should be made to keep pipetted samples free of gross debris. It is recommended that grossly turbid specimens be centrifuged before analysis. Frozen samples should be thawed and mixed prior to analysis. Adulteration of the urine sample may cause erroneous results. If adulteration is suspected, obtain another sample and forward both specimens to the laboratory for testing.

Handle all urine specimens as if they were potentially infectious.

Assay Procedure

Analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring enzymatic rates at 340 nm and timing the reaction accurately can be used to perform this assay.

Before performing the assay, refer to the analyzer-specific protocol sheet, which contains parameters and/or additional instructions for use.

Quality Control and Calibration

Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration. Control results must fall within established ranges, as determined by laboratory procedures and guidelines. If results fall outside of established ranges, assay results are invalid. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Each laboratory should establish its own calibration and control frequency.

Qualitative Analysis

For qualitative analysis of samples, use the DRI Multi-Drug Urine Calibrator 1 or 2. The Calibrator 1 contains 500 ng/mL d-methamphetamine, which is used as a cutoff reference for distinguishing "positive" from "negative" samples for a 500 ng/mL cutoff. The Calibrator 2 contains 1000 ng/mL d-methamphetamine, which is used as a cutoff reference for distinguishing "positive" from "negative" samples for a 1000 ng/mL cutoff.

Semi-quantitative analysis

For semi-quantitative analysis, use all calibrators.

Results and Expected Values

Qualitative results

A sample that exhibits a change in absorbance (ΔA) value equal to or greater than the value obtained with the cutoff calibrator is considered positive. A sample that exhibits a change in absorbance (ΔA) value lower than the value obtained with the cutoff calibrator is considered negative.

Semi-quantitative results

A rough estimate of drug concentration in the samples can be obtained by running a standard curve with all calibrators and quantitating samples off the standard curve. Sample results above the high calibrator should be diluted with negative urine and retested. Semi-quantitation of positive results enables laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC/MS. It also permits the laboratory to establish quality control procedures and assess control performance.

Limitations

1. A positive result from this assay indicates only the presence of amphetamine or methamphetamine and does not necessarily correlate with the extent of physiological and psychological effects.
2. A positive result by this assay should be confirmed by another nonimmunological method such as GC, TLC or GC/MS.
3. The test is designed for use with human urine only.
4. It is possible that other substances and/or factors (eg, technical or procedural) not listed in the specificity table may interfere with the test and cause false results.

Specific Performance Characteristics

Typical performance data results obtained on the Beckman Coulter AU680 analyzer are shown below.[11]

Dilution Recovery and Linearity

A high patient urine sample containing around 2000 ng/mL methamphetamine was serially diluted with analyte-free urine in 10% increments and tested in 5 replicates in semi-quantitative mode. All samples were recovered within ± 10% error of the expected value and the R-value was 0.9998.

Precision

Samples spiked with various amounts of d-amphetamine and d-methamphetamine were tested in qualitative and semi-quantitative mode using a CLSI (EP05-A2) precision protocol.[12] The samples were tested in replicates of 2, twice per day for 20 days, total N = 80. The results are presented in the following tables.

Qualitative Analysis:

Concentration of sample, ng/mL	Number of determinations	500 Cutoff #Neg / #Pos	1000 Cutoff #Neg / #Pos
d-Amphetamine			
0	80	80 / 0	80 / 0
150	80	80 / 0	80 / 0
375	80	80 / 0	80 / 0
625	80	0 / 80	80 / 0
750	80	0 / 80	80 / 0
1250	80	0 / 80	0 / 80
1500	80	0 / 80	0 / 80
d-Methamphetamine			
0	80	80 / 0	80 / 0
150	80	80 / 0	80 / 0
375	80	80 / 0	80 / 0
625	80	0 / 80	80 / 0
750	80	0 / 80	80 / 0
1250	80	0 / 80	0 / 80
1500	80	0 / 80	0 / 80

Semi-quantitative Analysis:

Sample Conc., ng/mL	Result Mean, ng/mL	Within-run Precision		Total Precision		500 Cutoff #Neg / #Pos	1000 Cutoff #Neg / #Pos
		SD, ng/mL	% CV	SD, ng/mL	% CV		
d-Amphetamine							
150	145.9	9.0	6.2	10.1	6.9	80 / 0	80 / 0
375	372.8	10.2	2.7	10.9	2.9	80 / 0	80 / 0
625	683.9	11.2	1.6	13.5	2.0	0 / 80	80 / 0
750	775.4	14.1	1.8	17.6	2.3	0 / 80	80 / 0
1250	1317.9	23.6	1.8	28.4	2.2	0 / 80	0 / 80
1500	1467.6	23.0	1.6	32.0	2.2	0 / 80	0 / 80
d-Methamphetamine							
150	168.4	7.4	4.4	9.3	5.5	80 / 0	80 / 0
375	392.8	8.0	2.0	11.1	2.8	80 / 0	80 / 0
625	626.1	9.6	1.5	12.1	1.9	0 / 80	80 / 0
750	770.4	9.7	1.3	11.8	1.5	0 / 80	80 / 0
1250	1284.1	15.5	1.2	18.9	1.5	0 / 80	0 / 80
1500	1515.1	21.4	1.4	27.3	1.8	0 / 80	0 / 80

Cutoff Characterization

Samples near the cutoff values were prepared by spiking d-amphetamine and d-methamphetamine separately into negative pooled urine. The samples were assayed in replicates of 20 in both qualitative and semi-quantitative modes. In qualitative mode, all samples were detected accurately with the negative samples recovering less than the cutoff calibrators and the positive samples recovering greater than the cutoff calibrators. In semi-quantitative mode, samples recovered within ± 12% error of their nominal values. The precision of the 20 replicates was less than 1% CV for qualitative mode and less than 4% CV for semi-quantitative mode.

Accuracy

160 clinical urine specimens were tested with the DRI Amphetamines assay on the Beckman Coulter AU680 and GC/MS. The results are presented in the following tables.

Some discordant results were obtained when the assay was used to detect amphetamine and methamphetamine analytes individually. The assay is capable of detecting the presence of both amphetamine and methamphetamine analytes with 100% cross reactivity to both drugs. Therefore samples tested for one analyte may give false positive results due to the presence of the other analyte.

Qualitative Analysis: The overall concordance between the DRI Amphetamines assay and GC/MS for amphetamine was 58.0% for the 500 cutoff and 59.4% for the 1000 cutoff.

Stratified Results

DRI	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (between -50% and cutoff)	Near Cutoff Positive by GC/MS (between cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Percent Agreement with GC/MS
500 ng/mL Cutoff					
Positive	34	24	14	49	100.0%
Negative	16	1	0	0	22.7%
1000 ng/mL Cutoff					
Positive	40	15	19	20	97.5%
Negative	35	8	1	0	43.9%

Qualitative

500 ng/mL GC/MS

DRI	+	-
+	63	58
-	0	17

1000 ng/mL GC/MS

DRI	+	-
+	39	55
-	1	43

Semi-quantitative Analysis: The overall concordance between the DRI Amphetamines assay and GC/MS for amphetamine was 58.0% for the 500 cutoff and 58.7% for the 1000 cutoff.

Stratified Results

DRI	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (between -50% and cutoff)	Near Cutoff Positive by GC/MS (between cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Percent Agreement with GC/MS
500 ng/mL Cutoff					
Positive	34	24	14	49	100.0%
Negative	16	1	0	0	22.7%
1000 ng/mL Cutoff					
Positive	41	15	19	20	97.5%
Negative	34	8	1	0	42.9%

Semi-quantitative

500 ng/mL GC/MS

DRI	+	-
+	63	58
-	0	17

1000 ng/mL GC/MS

DRI	+	-
+	39	56
-	1	42

Summary of Amphetamine Discordant Results:
Accuracy samples were categorized based upon the d-amphetamine GC/MS concentration only. The table below identifies those samples with a d-amphetamine concentration below the cutoff, in which the observed DRI Amphetamines assay result was positive.

Cutoff Value (ng/mL)	DRI Result	Amphetamine GC/MS (ng/mL)	Methamphetamine GC/MS (ng/mL)
500	Positive	47	1653
500	Positive	68	1621
500	Positive	68	334
500	Positive	69	1666
500	Positive	69	1707
500	Positive	70	444
500	Positive	70	1513
500	Positive	76	1679
500	Positive	82	533
500	Positive	83	481
500	Positive [a]	100	538
500	Positive	100	675
500	Positive	109	1446
500	Positive	123	661
500	Positive	128	503
500	Positive	128	1221
500	Positive	141	1259
500	Positive	148	942
500	Positive	160	1254
500	Positive	161	1415
500	Positive	168	1319
500	Positive	168	1595
500	Positive	184	548
500	Positive	189	1067
500	Positive	200	1024
500	Positive	202	393
500	Positive	203	1230
500	Positive	211	1421
500	Positive	212	1241
500	Positive	214	97
500	Positive	231	1782
500	Positive	232	207
500	Positive	140	449
500	Positive	246	460
500	Positive	258	1029
500	Positive	264	1642
500	Positive	270	479
500	Positive	271	1338
500	Positive	272	1080
500	Positive	273	516
500	Positive	298	2772
500	Positive	300	101
500	Positive	307	2411
500	Positive	317	2668
500	Positive	325	2828
500	Positive	330	2543
500	Positive	374	693
500	Positive	380	709

Table con't

Cutoff Value (ng/mL)	DRI Result	Amphetamine GC/MS (ng/mL)	Methamphetamine GC/MS (ng/mL)
500	Positive	402	132
500	Positive	407	747
500	Positive	417	1088
500	Positive	426	1599
500	Positive	450	828
500	Positive	486	860
500	Positive	490	1287
500	Positive	493	1005
500	Positive	494	924
500	Positive	498	919
1000	Positive	47	1653
1000	Positive	68	1621
1000	Positive	68	334
1000	Positive	69	1666
1000	Positive	69	1707
1000	Positive	70	1513
1000	Positive	76	1679
1000	Positive	100	538
1000	Positive	109	1446
1000	Positive	128	1221
1000	Positive	141	1259
1000	Positive	148	942
1000	Positive	160	1254
1000	Positive	161	1415
1000	Positive	168	1319
1000	Positive	168	1595
1000	Positive	189	1067
1000	Positive	200	1024
1000	Positive	203	1230
1000	Positive	211	1421
1000	Positive	212	1241
1000	Positive	231	1782
1000	Positive	258	1029
1000	Positive	264	1642
1000	Positive	271	1338
1000	Positive	272	1080
1000	Positive	298	2772
1000	Positive	307	2411
1000	Positive	317	2668
1000	Positive	325	2828
1000	Positive	330	2543
1000	Positive	374	693
1000	Positive	407	747
1000	Positive	417	1088
1000	Positive	426	1599
1000	Positive	450	828
1000	Positive	486	860
1000	Positive	490	1287
1000	Positive	493	1005

Table con't

Cutoff Value (ng/mL)	DRI Result	Amphetamine GC/MS (ng/mL)	Methamphetamine GC/MS (ng/mL)
1000	Positive	494	924
1000	Positive	498	919
1000	Positive	500	1989
1000	Positive	513	938
1000	Positive	522	957
1000	Positive	541	1013
1000	Positive	572	1050
1000	Positive	576	1052
1000	Positive	595	2396
1000	Positive	656	2533
1000	Positive	715	2415
1000	Positive	771	1190
1000	Positive	780	287
1000	Positive	814	2984
1000	Positive [b]	816	0
1000	Positive	929	0
1000	Positive	998	367
1000	Negative	1101	0

Qualitative Analysis: The overall concordance between the DRI Amphetamines assay and GC/MS for methamphetamine was 87.4% for the 500 cutoff and 87.4% for the 1000 cutoff.

Stratified Results

DRI	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (between -50% and cutoff)	Near Cutoff Positive by GC/MS (between cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Percent Agreement with GC/MS
500 ng/mL Cutoff					
Positive	3	11	11	60	100.0%
Negative	19	7	0	0	65.0%
1000 ng/mL Cutoff					
Positive	5	9	22	31	100.0%
Negative	35	9	0	0	75.9%

Qualitative

500 ng/mL GC/MS

DRI	+	-
+	71	14
-	0	26

1000 ng/mL GC/MS

DRI	+	-
+	53	14
-	0	44

Stratified Results

DRI	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (between -50% and cutoff)	Near Cutoff Positive by GC/MS (between cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Percent Agreement with GC/MS
500 ng/mL Cutoff					
Positive	3	11	11	60	100.0%
Negative	19	7	0	0	65.0%
1000 ng/mL Cutoff					
Positive	5	10	22	31	100.0%
Negative	34	8	0	0	74.1%

Semi-quantitative

500 ng/mL GC/MS

DRI	+	-
+	71	14
-	0	26

1000 ng/mL GC/MS

DRI	+	-
+	53	15
-	0	43

Summary of Methamphetamine Discordant Results:
Accuracy samples were categorized based upon the d-methamphetamine GC/MS concentration only. The table below identifies those samples with a d-methamphetamine concentration below the cutoff, in which the observed DRI Amphetamines assay result was positive.

Cutoff Value (ng/mL)	DRI Result	Amphetamine GC/MS (ng/mL)	Methamphetamine GC/MS (ng/mL)
500	Positive	300	101
500	Positive	402	132
500	Positive	232	207
500	Positive	780	287
500	Positive	68	334
500	Positive	1142	339
500	Positive	1203	356
500	Positive	998	367
500	Positive	202	393
500	Positive	70	444
500	Positive	240	449
500	Positive	246	460
500	Positive	270	479
500	Positive	83	481
1000	Positive	780	287
1000	Positive	68	334
1000	Positive	1142	339
1000	Positive	1203	356
1000	Positive	998	367
1000	Positive	100	538
1000	Positive	374	693
1000	Positive	407	747
1000	Positive	450	828
1000	Positive	486	860
1000	Positive	498	919
1000	Positive	494	924
1000	Positive	513	938
1000	Positive	148	942
1000	Positive	522	957

[a] Sample also contained MDA~288 ng/mL and MDMA~2530 ng/mL.
[b] Sample also contained PPA ~1000 ng/mL and Pseudoephedrine ≥ 40 µg/mL.

Specificity

The specificity of the assay was evaluated by testing various structurally related and unrelated compounds for cross-reactivity. The potential cross-reactant compound was spiked into a negative urine pool at the listed concentrations and tested in qualitative and semi-quantitative mode. Samples that tested positive or greater than the cutoff concentration were considered to cross react with the assay and samples that tested negative or less than the cutoff concentration were considered to have no significant cross reactivity.

The following parent compound and metabolites, when tested with the DRI Amphetamines assay, produced a positive result at the concentrations listed below.

Compound	500 Cutoff Concentration, ng/mL	1000 Cutoff Concentration, ng/mL
d-Amphetamine	500	1000
d-Methamphetamine	500	1000
Methylenedioxyamphetamine (MDA)	1400	2500
Methylenedioxymethamphetamine (MDMA)	800	1300

Structurally unrelated compounds and/or concurrently used drugs produced a negative result at the concentrations listed below.

Compound	500 Cutoff Concentration, ng/mL	1000 Cutoff Concentration, ng/mL
Acetaminophen	1000000	1000000
Acetylsalicylic Acid	1000000	1000000
l-Amphetamine	12500	12500
Benzoylecgonine	1000000	1000000
Benzphetamine	20000	20000
Benzylpiperazine	40000	63000
Bupropion	13000	50000
Caffeine	1000000	1000000
Cetirizin Dihydrochloride	1000000	1000000
Chlorpromazine	500000	500000
Codeine	1000000	1000000
Dextromethorphan	1000000	1000000
d-Ephedrine	1000000	2000000
l-Ephedrine	100000	350000
d,l-Ephedrine	200000	700000
Fenfluramine	1200	4000
Isometheptene	6000	20000
Isoxsuprine	100000	100000
Meperidine	1000000	1000000
Mephentermine	15000	25000
Methadone	1000000	1000000
l-Methamphetamine	3500	10000
Methapyrilene	100000	500000
Methylphenidate	150000	500000
Metronidazole	1000000	1000000
Morphine	1000000	1000000
Nor-pseudoephedrine	600000	1000000
Oxazepam	500000	500000
Phencyclidine	1000000	1000000
Phendimetrazine	40000	200000
Phenethylamine	30000	100000
Phenmetrazine	1500	4000
Phenobarbital	1000000	1000000
Phenothiazine	10000	10000
Phentermine	17500	25000
Phenylephrine	300000	500000
Phenylpropanolamine	200000	250000
Procainamide	13000	20000
Promethazine	500000	500000

Table con't

Compound	500 Cutoff Concentration, ng/mL	1000 Cutoff Concentration, ng/mL
Propranolol	200000	200000
d-Pseudoephedrine	75000	250000
l-Pseudoephedrine	150000	250000
Ranitidine	250000	600000
Scopolamine	35000	100000
Secobarbital	1000000	1000000
Thioridazine	1000000	1000000
Trifluoperazine	1000000	1000000
Triflupromazine	1000000	1000000
Tyramine	300000	500000
3-OH-Tyramine	500000	500000

Interference

The potential effects of pH, endogenous and exogenous substances on the recovery of amphetamines using the DRI Amphetamines assay was assessed by adding known amounts of potentially interfering substances into two pools of drug free urine containing the highest concentration of amphetamine and methamphetamine that gives a consistently negative result, and the lowest concentration of amphetamine and methamphetamine that gives a consistently positive result, between ± 25% of the cutoff value. The samples were tested in both qualitative and semi-quantitative modes. No interference was observed by the addition of the compounds up to the concentrations listed in the following table.

Drug: Amphetamine, Methamphetamine		500 Cutoff (NEG/POS)		1000 Cutoff (NEG/POS)	
Interferent Compound	Compound Concentration	Neg level	Pos level	Neg level	Pos level
Acetaminophen	100 µg/mL	Neg	Pos	Neg	Pos
Acetone	1 g/dL	Neg	Pos	Neg	Pos
Ascorbic acid	1 g/dL	Neg	Pos	Neg	Pos
Aspirin	100 µg/mL	Neg	Pos	Neg	Pos
Caffeine	100 µg/mL	Neg	Pos	Neg	Pos
Creatinine	500 mg/dL	Neg	Pos	Neg	Pos
Ethanol	1 g/dL	Neg	Pos	Neg	Pos
Galactose	10 mg/dL	Neg	Pos	Neg	Pos
γ-globulin	500 mg/dL	Neg	Pos	Neg	Pos
Glucose	3 g/dL	Neg	Pos	Neg	Pos
Hemoglobin	150 mg/dL	Neg	Pos	Neg	Pos
Human serum albumin	500 mg/dL	Neg	Pos	Neg	Pos
Ibuprofen	100 µg/mL	Neg	Pos	Neg	Pos
Oxalic acid	100 mg/dL	Neg	Pos	Neg	Pos
pH Range	3 - 11	Neg	Pos	Neg	Pos
Riboflavin	7.5 mg/dL	Neg	Pos	Neg	Pos
Sodium chloride	1 g/dL	Neg	Pos	Neg	Pos
Specific Gravity	1.004-1.038 g/mL	Neg	Pos	Neg	Pos
Urea	1.25 g/dL	Neg	Pos	Neg	Pos

References

1. *Urine Testing for Drugs of Abuse*. National Institute on Drug Abuse (NIDA). Research Monograph 73, 1986.
2. *Mandatory Guidelines for Federal Workplace Drug Testing Programs.* National Institute On Drug Abuse. Federal Register Vol. 73, No. 228, 2008:71877.
3. Julien RM. A Primer of Drug Action. 6th ed. New York, NY: WH Freeman & Co; 1992.
4. Miller NS, Gold MS. Amphetamine and its derivatives. In: Giannini AJ, Slaby AE, eds. *Drugs of Abuse.* Oradell, NJ: Medical Economics Books; 1989.
5. Baselt RC. *Disposition of Toxic Drugs and Chemicals in Man*, 5th ed. Foster City, CA: Chemical Toxicology Institute; 2000.
6. Rubenstein KE, Schneider RS, and EF Ullman: Homogenous Enzyme Immunoassay: A New Immunochemical Technique. Biochem Biophys Res Commun. 1972:47, 846.
7. Jimenez, et al, Stability Studies of amphetamine and ephedrine derivatives in urine. *Journal of Chromatography B*, (2006) 84:93.
8. Drugs of Abuse, *Clinical Reference Laboratory,* Inc., (2009) 4.
9. C52-A2, Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline – Second Edition, *Clinical and Laboratory Standards Institute (CLSI)* (April 2007).
10. *Notice of Mandatory Guidelines for Federal Workplace Drug Testing Program: Final Guidelines; Federal Register*, Substance Abuse and Mental Health Administration (SAMHSA), (1994) 110 (June 9):11983.
11. Data on file at Microgenics Corporation, a part of Thermo Fisher Scientific.
12. Clinical and Laboratory Standards Institute. *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline*. 2nd ed. Wayne, PA: Clinical and Laboratory Standards Institute; NCCLS EP05-A2 Document. 2004.

Glossary:
http://www.thermofisher.com/symbols-glossary

Microgenics Corporation,
part of Thermo Fisher Scientific
46500 Kato Road
Fremont, CA 94538 USA
US Customer and Technical Support:
1-800-232-3342

EC REP
B·R·A·H·M·S GmbH
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